# **EXHIBIT 1**

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COUNSEL FOR PLAINTIFF AND THE CLASS

International Union of Operating Engineers, Local No. 68 Welfare Fund,

Plaintiff.

AstraZeneca PLC; AstraZeneca Pharmaceuticals LP; AstraZeneca LP; Zeneca, Inc.; TAP Pharmaceutical Products, Inc.; Abbott Laboratories; Takeda Chemical Industries, Ltd.; Bayer AG, Bayer Corporation; Miles Laboratories, Inc.; Cutter Laboratories, Inc.; GlaxoSmithKline, P.L.C.; SmithKline Beecham Corporation; Glaxo Wellcome, Inc.; Pharmacia Corporation; Pharmacia & Upjohn, Inc.: Monsanto Company; G.D. Searle Company; Sanofi-Synthelabo Inc.: Johnson & Johnson; Alza Corporation; Centocor, Inc.; Ortho Biotech, Inc.; Alpha Therapeutic Corporation: Hoffman La-Roche Inc.; Amgen, Inc.; Immunex Corporation; Aventis Pharmaceuticals, Inc.; Aventis Behring L.L.C.; Hoechst Marion Roussel, Inc.; Centeon, L.L.C.; Armour Pharmaceuticals; Baxter International Inc.; Baxter Healthcare Corporation; Immuno-U.S., Inc.; Boehringer Ingelheim Corporation: Ben Venue Laboratories, Inc.; Bedford Laboratories: Roxane Laboratories, Inc.; Bristol-Myers Squibb Company: Oncology Therapeutics Network Corporation; Apothecon, Inc.; Dey, Inc.; Fujisawa Pharmaceutical Co., Ltd.; Fujisawa Healthcare, Inc.; Fujisawa USA, Inc.; Novartis International AG; Novartis Pharmaceutical Corporation; Sandoz Pharmaceutical Corporation; Schering-Plough Corporation; Warrick Pharmaceuticals Corporation; Sicor, Inc.; Gensia Sicor Pharmaceuticals, Inc.; Wyeth; Wyeth Pharmaceuticals; Saad Antoun, M.D.; Stanley C. Hopkins, M.D.; Robert A. Berkman, M.D.; Does 1-50; ABC Corporations 1-50; and XYZ Partnerships; and

Defendants.

SUPERIOR COURT OF NEW JERSEY

**EQUITY DIVISION** 

MONMOUTH COUNTY

CIVIL ACTION NO.

193 03

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

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Associations 1-50,

<sup>° 2003</sup> KLINE & SPECTER

## **CLASS ACTION COMPLAINT**

Plaintiff, International Union of Operating Engineers, Local No. 68 Welfare Fund ("Plaintiff"), by its attorneys, brings this Complaint on its own behalf, and on behalf of all others similarly situated, pursuant to the common law and statutes of New Jersey, to obtain declaratory and injunctive relief, damages, costs of suit, attorneys' fees and other appropriate relief from the Defendants. Plaintiff and the Class it seeks to represent make no claim under any federal law, including ERISA and Medicare, and expressly disavow any right to recover under any federal law, including ERISA and Medicare, to the extent any such right exists under the facts alleged herein and further expressly disavows any so-called "Best Price" claim. Plaintiff complains and alleges, upon information and belief, as follows:

#### NATURE OF THE CASE

1. This case is brought by Plaintiff, International Union of Operating Engineers, Local No. 68 Welfare Fund, as a class action on behalf of hundreds of thousands of individuals and entities to recover monies overpaid as a result of Defendants' fraudulent scheme and conspiracy that targeted at least three (3) types of healthcare patients: (1) "Government Assistance Patients": those who subscribe to and rely on one or more government assistance programs for the partial payment of their medical care and treatment (hereinafter referred to collectively as "government assistance programs"); (2) "Private Assistance Patients": those who subscribe to and rely on private health insurance carriers and programs for the partial payment of their medical care and treatment; and (3) "No Assistance Patients": those who have no insurance at all for the payment of their medical care and treatment.

# CANCER, INHALANT AND MISCELLANEOUS OTHER DRUGS INCLUDED IN THIS ACTION

- 2. Government assistance programs administered by the federal government, for the most part, do not cover the cost of prescription drugs. However, such programs typically do cover the cost of drugs administered by or under the supervision of a medical physician. These drugs include many intravenously-administered drugs, a large number of which are infused in the doctor's office, as well as drugs administered by implanted delivery systems, and drugs for inhalation administered by nebulizer equipment, among others.
- 3. Drugs administered intravenously under the supervision of a physician include drugs which fall within the broad class of cancer (anti-neoplastic) medications. Drugs in the anti-neoplastic class are administered according to the type, class, and stage of the cancer that is being treated. For example, paclitaxel (Anzatax®, Biotax®) is indicated for treatment of forms of lung cancer, breast cancer, ovarian cancer and Kaposi's sarcoma. More than one drug within the class may be indicated for the treatment of a specific type of cancer. For instance, etoposide (Etoposide, Etopophos, Toposar) is also used in the treatment of breast cancer. Prostate cancer is treated with primary and secondary antihormonal medications. Primary antihormonals, include leuprolide acetate (Lupron®, Viadur®, Trelstar™ and Eligard™) and goserelin acetate (Zoladex®). Secondary antihormonals include bicalutamide (Casodex®), flutamide (Eulexin®), and nilutamide (Nilandron®). Other medications to treat prostate cancer include the hormone megestrol (Megace®) and the chemotherapeutic agent etramustine phosphate (Emcyt®).
- 4. Drugs used in the treatment of cancer have other effects in addition to their anti-neoplastic actions. These effects are often referred to as side effects. The most frequent side effects reported among anti-cancer agents are anemia (decreased numbers of red blood cells),

hypercalcemia (increased calcium), nausea, and decreased immune capacity to fight bacterial, fungal and viral infections. There is a wide variety of drugs available for the specific treatment of these side effects, many of which are also administered by a physician and therefore covered by government assistance programs. Drugs used to treat the various deficiencies of blood cells include the crythropoietin class of drugs (Procrit<sup>®</sup>, Aranesp<sup>™</sup>, Epogen<sup>®</sup>), the anti-neutropenic drugs (Neupogen<sup>®</sup>, Leukine<sup>®</sup>) and anti-thrombocytopenic drugs (Neumega<sup>®</sup>). Production of other blood cells made in the bone marrow may be decreased by anticancer drugs including white blood cells (leukopenia) and platelets (thrombocytopenia). Intravenously administered, and therefore physician-administered, medications to combat hypercalcemia include drugs like Aredia<sup>®</sup> and Didronel<sup>®</sup>. Anti-nausea medications given intravenously at the time of administration of anti-cancer drugs that cause nausea include Anzemet<sup>®</sup>, Zofran<sup>®</sup>, Kytril<sup>®</sup>, and Reglan<sup>®</sup>.

- 5. Patients with immune deficiencies, such as patients undergoing cancer chemotherapy, organ transplant patients, and patients with HIV/AIDS require intravenous administration of antibiotics, antifungal drugs and antiviral medications, as well as specific plasma proteins and immune globulins.
- 6. There are other medical conditions that involve the use of physician-administered medications, or medications given through specialized delivery systems that are covered by government assistance programs. Medications for patients who are undergoing dialysis, such as agents to combat hypocalcemia (decreased serum calcium) like Calciject® and Zemplar®, and the antianemic drugs of the erythropoetin type, may be intravenously administered. Patients with hemophilia require the intravenous administration of blood clotting factors such as factor VIII (Bioclate, Helixate, Humate-P, Monoclate-P, Hemofil M, Kogenate®, Koate®) and factor IX (Mononine, Bebulin).

- 7. Government assistance programs also cover medications for the treatment of obstructive airways diseases that are administered with the use of a nebulizer, such as albuterol (Proventil<sup>®</sup>, Alupent<sup>®</sup>, Ventolin<sup>®</sup>, and Flovent<sup>®</sup>), cromolyn sodium (Intal<sup>®</sup> and generics) and ipratroprium bromide (Atrovent<sup>®</sup>, Combivent<sup>®</sup> and DuoNeb<sup>®</sup>).
- 8. Many intravenously-administered medications must be mixed with various solutions. These solutions contain sodium chloride, dextrose, or various combinations thereof, which are also covered by government assistance programs, as are various plasma components and expanders used in the treatment of plasma volume deficiency.
- 9. Medications administered by or under the direct supervision of a physician and/or prescribed by a physician and covered for reimbursement under government assistance programs therefore cover a broad spectrum of classes and indications. Drug manufacturers who produce, market and sell medications which fall within these classes, and may be identical or very similar and have identical or closely-related indications, thus have aligned interests in ensuring that their drugs continue to be prescribed and covered by and reimbursed under government and private assistance programs.
- 10. The drugs described above that are included in this lawsuit may be generally classified into three (3) areas: (1) "cancer drugs," (2) "inhalant drugs," and (3) "miscellaneous other drugs" covered under government and/or private assistance programs, and/or paid for or reimbursed at a cost based, in whole or part, on the average wholesale price (or "AWP") for such drugs (or the AWP for the equivalent or "Least Costly Alternative" ["LCA"] after LCA-based reimbursement methodologies were adopted in New Jersey.
- 11. "Cancer drugs" include drugs used in the treatment of cancer (i.e., antineoplastic drugs), as well as drugs that are prescribed in conjunction with cancer treatment (i.e., antianemic, 2003 KLINE & SPECTER 5

antihypercalcemic, antineotropenic, antihormonal drugs as described above). Examples of these drugs include: bicalutamide, calcitral carboplatin, cisplatin, docetaxel, doxorubicin, epoetin alpha, etoposide, factor VIII, factor IX, filgrastim, flutamide, goserelin acetate, granisetron, leuprolide acetate, megestrol, nilutamide, and ansetron, paclitaxel, and tamoxifen, among others.

- 12. "Inhalant drugs" include drugs used in the treatment of various breathing disorders, including such serious conditions as Chronic Obstructive Pulmonary Disease ("COPD"). Examples of these drugs include: albuterol sulfate, cromolyn sodium and ipratropium bromide.
- 13. "Miscellaneous other drugs" include drugs used to treat various medical conditions, including cardiac and kidney problems, immune deficiencies, hemophilia, organ transplants, etc., (i.e., antihemorrahagic, antihemophilic, antidiabetic, immunosuppressant drugs). Examples of these drugs include: acyclovir, cyclosporine, dexamethasone, factor VIII, mycophenotate mofetil, tacrolimus, and vancomycin, among others.

# SUMMARY OF CLAIMS

- During the period from at least 1991 through the present, the exact dates of which are unknown by the plaintiff at this time, defendants created and implemented a fraudulent marketing, pricing, sales and distribution scheme to defraud plaintiff and the Class by substantially increasing the sales of cancer, inhalant and miscellaneous other drugs and reaping unlawful profits at the expense of patients who took these drugs and paid for them.
- 15. Among other things, defendants systematically, among themselves and with other entities and individuals, created a pervasive illegal system to cause patients on cancer, inhalant and miscellaneous other drugs to overpay substantial amounts of money for the specific purpose of increasing the market share of these drugs and maximizing corporate profits at the expense of plaintiff and the Class. The improper marketing, pricing, sales and distribution practices relate to,

inter alia, the following: (a) deliberately overstating the Average Wholesale Prices (or "AWPs") for cancer, inhalant and miscellaneous other drugs, the rates upon which reimbursements under government and private assistance programs are made, including the co-payment portions paid by government and private assistance patients and their carriers, so that the plaintiff and the Class paid artificially inflated amounts of money for cancer, inhalant and miscellaneous other drugs; (b) providing and distributing free samples of these drugs to medical providers and instructing them that they could and should bill plaintiff and the Class for such free samples; (c) providing other unlawful inducements to medical providers to prescribe these drugs, causing plaintiff and the Class to pay artificially inflated prices for these drugs; and (d) working in concert with each other and others to circumvent efforts to reduce prescription drug costs.

- 16. Because of the unlawful conduct of all of the defendants, plaintiff and the Class paid artificially inflated prices for cancer, inhalant and miscellaneous other drugs.
- 17. On behalf of plaintiff and the Class, this action seeks compensatory and punitive damages, statutory damages and equitable relief, including restitution and mandatory and prohibitive injunctive relief, among other forms of relief. It seeks, on behalf of plaintiff and the Class, the imposition of fines, civil penalties, restitution and other monetary relief against each of the defendants.

#### JURISDICTION AND VENUE

- 18. Plaintiff has asserted claims exclusively under the common law and statutes of New Jersey. No federal claim is asserted.
- 19. Plaintiff brings this action exclusively pursuant to consumer protection laws of New Jersey, as well as the New Jersey common law. No aspect of the claims asserted in this Class Action Complaint is brought pursuant to any federal law, including either ERISA or Medicare, and thus no 2003 KLINE & SPECTER 7

federal question is raised by any of the claims asserted. To the extent any of plaintiff claims or factual allegations herein may be construed to have stated any claim under federal law, such claim is expressly and underiably disavowed and disclaimed by plaintiff and the Class. Moreover, to the extent any of plaintiff' claims or factual allegations herein are urged by any Defendant to have stated any claim under federal law, plaintiff expressly disavows such claims or allegations and reserves the right to modify this Complaint to conform its claims.

- 20. This Court has subject matter jurisdiction because this is an action for damages which, in the aggregate, exceeds \$10,000.00 exclusive of interest, costs and attorneys' fees.
- 21. This Court has jurisdiction over the Defendants because they are corporations regulated under the laws of the State of New Jersey and are present or located in, do sufficient business in, have sufficient minimum contacts with, and/or otherwise intentionally avail themselves of the laws and markets of the State of New Jersey through the manufacture, promotion, marketing, distribution and sale of drugs and products in New Jersey.
- 22. Venue is proper in this Court since plaintiff, as well as numerous Class members, were prescribed and paid for cancer, inhalant and miscellaneous other drugs from doctors, hospitals and others located in this County and throughout New Jersey, and otherwise engaged in the transactions which form the basis of this action by having paid for these drugs. In particular, defendant Saad Antoun, M.D. resides and works in this County.

# THE PARTIES

# Plaintiff

23. Plaintiff, International Union of Operating Engineers, Local No. 68 Welfare Fund, resides in the State of New Jersey.

- Plaintiff and the Class paid for cancer, inhalant and miscellaneous other drugs manufactured, marketed, distributed and sold by defendants in New Jersey and throughout the country and were charged and paid a price based in whole or in part on the AWP for these drugs each time. Among other drugs, plaintiff and the Class have paid for the following: acyclovir, albuterol sulfate, bicalutamide, bleomycin, calcitrol, carboplatin, cisplatin, cromolyn sodium, cyclosporine, darbepoetin alfa, dexamethosone, docetaxel, dolasetron mesylate, doxorubicin hydrochloride, epoetin alpha, etidronate disodium, etoposide, Factor VIII, Factor IX, filgrastim, flutamide, glyburide, goserelin acetate, granisetron, heparin sodium, ipratropium bromide, ironatecan, leucovorin calcium, lansoprazole, metaproterenol, mycophenolate mofetil, omeprazole, ondansetron, paclitaxel, pamidronate disodium, tacrolimus, tamoxifen, triptorelin pamoate and vancomycin, as well as other cancer (antineoplastic, antianemic, antihypercalcemic, and antineotropenic), inhalant, and miscellaneous other (antihemorrahagic, antihemophilic, antidiabetic, and immunosuppressant) drugs not listed herein. These drugs were manufactured, distributed, marketed and sold by the defendants named herein.
- 25. Accordingly, plaintiff and the Class suffered direct injury and damages as a result of the unlawful conduct of all of the defendants set forth herein.

#### The Defendants

26. The Defendants are AstraZeneca PLC, AstraZeneca Pharmaceuticals LP, AstraZeneca LP, Zeneca, Inc., TAP Pharmaceutical Products, Inc., Abbott Laboratories, Takeda Chemical Industries, Ltd., Bayer AG, Bayer Corporation, Miles Laboratories, Inc., Cutter Laboratories, Inc., GlaxoSmithKline, P.L.C., SmithKline Beecham Corporation, Glaxo Wellcome, Inc., Pharmacia Corporation, Pharmacia & Upjohn, Inc., Monsanto Company, G.D. Searle, Sanofi-Synthelabo, Inc., Johnson & Johnson, Alza Corporation, Centocor, Inc., Ortho Biotech, Alpha Therapeutic 2003 KLINE & SPECTER

Corporation, Hoffman La-Roche Inc., Amgen, Inc., Immunex Corporation, Aventis Pharmaceuticals, Inc., Aventis Behring L.L.C., Hoechst Marion Roussel, Inc., Centeon, L.L.C., Armour Pharmaceuticals, Baxter International Inc., Baxter Healthcare Corporation, Immuno-U.S., Inc., Boehringer Ingelheim Corporation, Ben Venue Laboratories, Inc., Bedford Laboratories, Roxane Laboratories, Inc., Bristol-Myers Squibb Company, Oncology Therapeutics Network Corporation, Apothecon, Inc., Dey, Inc., Fujisawa Pharmaceutical Co., Ltd., Fujisawa Healthcare, Inc., Fujisawa USA, Inc., Novartis International AG, Novartis Pharmaceutical Corporation, Sandoz Pharmaceutical Corporation, Schering-Plough Corporation, Warrick Pharmaceuticals Corporation, Sicor, Inc., Gensia Sicor Pharmaceuticals, Inc., Wyeth, Wyeth Pharmaceuticals, Saad Antoun, M.D., Stanley C. Hopkins, M.D. and Robert A. Berkman, M.D. [The foregoing corporate defendants, the individual defendants and various "doe" defendants, "ABC" corporations, and "XYZ" partnerships and associations whose names and identifies are not yet known are collectively referred to herein as "defendants."]

27. Defendant, AstraZeneca PLC ("AstraZeneca PLC"), the third largest pharmaceutical company in the world, is a British corporation with its corporate headquarters, located at 15 Stanhope Gate, London W1K 1LN, U.K. AstraZeneca PLC was formed on April 6, 1999 through the merger of Astra AB of Sweden and Zeneca Group PLC of the United Kingdom. AstraZeneca PLC researches, develops, and manufactures generic and brand name pharmaceutical drugs for use in seven therapeutic areas: cardiovascular, central nervous system, gastrointestinal, infection, oncology, pain control and anaesthesia, and respiratory. One of Zeneca Group PLC's key products, which it brought with it to the merger, was Zoladex® (goserelin acetate). Like its competitor, Lupron®, Zoladex® is used in the treatment of prostate cancer in men, endometriosis and infertility in women, and central precocious puberty in children.

- Defendant, AstraZeneca Pharmaceuticals LP ("AstraZeneca"), is a Delaware limited partnership with its headquarters located at 1800 Concord Pike, Wilmington, Delaware 19850. AstraZeneca manufactures, markets, sells and distributes cancer and miscellaneous other drugs, like Zoladex®, throughout New Jersey and the United States.
- Defendant, AstraZeneca LP ("AstraZeneca LP"), is a limited partnership with its principal place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087. AstraZeneca LP maintains an additional facility in Westborough, Massachusetts. AstraZeneca LP is a developer and manufacturer of cancer and miscellaneous other drugs.
- 30. Defendant, Zeneca, Inc. ("Zeneca"), is a Delaware corporation with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850. Until April 1999, Zeneca, Inc. was a subsidiary of Zeneca Group PLC (UK).
- 31. Defendants, AstraZeneca PLC, AstraZeneca Pharmaceuticals LP, AstraZeneca LP and Zeneca, Inc. [hereinafter the "AstraZeneca Defendants"], are manufacturers, marketers, promoters, sellers and distributors of cancer and miscellaneous other drugs, including the aforementioned Zoladex<sup>®</sup>, and Casodex<sup>®</sup> (bicaltumide), Arimidex<sup>®</sup> (anastrozole), Deprivan (propofol), Nolvadex (tamoxifen), Cefotan, Elavil Injection, Faslodex, Foscavir, Merrem, Tenormin Injection, Tomodex (ralitrexed), Xylocaine Injection, Prilosec® (omeprazole) and Nexium (esomeprazole), direct competitor drugs of TAP's Prevacid On June 23, 2003, it was reported that one or more of the AstraZeneca Defendants pled guilty to violating federal law by inflating the AWP for Zoladex and conspiring with doctors to bill for free samples of the drug. The AstraZeneca Defendants paid \$354.9 million in damages and fines. In light of, inter alia, one or more of the AstraZeneca Defendants agreement to settle civil and criminal charges with the federal government, it is believed and therefore averred that the AstraZeneca Defendants engaged in

unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer, and miscellaneous other drugs that are paid for by plaintiff and the Class.

- Takeda Chemical Industries, Ltd. and Abbott Laboratories. TAP's United States headquarters is located at 675 North Field Drive, Lake Forest, Illinois 60045. Under a partnership agreement between Abbott and Takeda, TAP (owned 50 percent by Abbott and 50 percent by Takeda), together with its subsidiary, TAP Pharmaceuticals, Inc., develops, markets, promotes, and sells pharmaceutical products for the United States and Canada. One of these drugs is Lupron<sup>®</sup> (leuprolide acetate for depot suspension), which, like Zoladex<sup>®</sup>, is used in the treatment of prostate cancer in men, endometriosis and infertility in women, and central precocious puberty in children. Since Lupron<sup>®</sup> is the subject of a class action case pending in Cape May County against TAP, Abbott and Takeda, no claim is made herein for Lupron<sup>®</sup> damages against these defendants. However, to extent other defendants participated in a fraudulent scheme and conspiracy, which had the effect of causing damages for Lupron<sup>®</sup>, the claims set forth herein include the joint and several liability of these defendants for Lupron<sup>®</sup>. Another of these drugs is Prevacid<sup>®</sup> (lansoprazole), which, like Prilosec<sup>®</sup>, is used to treat peptic ulcer disease and gastro-esophageal reflux disease.
- 33. Defendant, Abbott Laboratories ("Abbott"), is a highly diversified healthcare corporation the principal business of which is the discovery, development, manufacture, and sale of a broad and diversified line of health care products and services. Abbott's business includes pharmaceuticals, nutritionals, hospital products, and diagnostics. Abbott's world headquarters is located in Abbott Park, Illinois. Abbott manufactures, markets, sells and distributes numerous

cancer and miscellaneous other drugs which are sold throughout New Jersey and the United States. Moreover, Abbott distributes Prevacid and Lupron for TAP.

- Defendant, Takeda Chemical Industries, Ltd. ("Takeda"), is Japan's largest pharmaceutical company and is among the largest in the world. Headquartered in Osaka, Japan. Takeda discovers, develops, manufactures and markets a broad range of pharmaceutical products. Takeda Pharmaceuticals America was created to take advantage of Takeda's growing, international pharmaceutical presence. Takeda Pharmaceuticals America's U.S. headquarters is in Lincolnshire, Illinois. Takeda manufactures, markets, sells and distributes numerous prescription drugs, vitamins and pharmaceutical products throughout New Jersey and the United States. Moreover, Takeda manufactures and ships Prevacid and Lupron to the United States.
- 35. Defendants, Abbott, Takeda and TAP, through Defendant TAP, have pleaded guilty to federal criminal and civil fraud charges for, among other things, conspiring to violate the Prescription Drug Marketing Act ("PDMA") by, inter alia, providing free samples of Lupron® to medical providers and encouraging them to charge Medicare, other insurance programs and patients in New Jersey and throughout the United States for those free samples. This conspiracy was in violation of the federal conspiracy statute, 18 U.S.C. § 371 (Conspiracy to Commit Offense or to Defraud United States). TAP agreed to pay over \$890 million in fines and civil penalties to the federal government and the states, of which a portion was paid to New Jersey. The government agreed not to prosecute Abbott and Takeda in return for TAP's compliance with the plea agreement. As part of its plea agreement, TAP included both of its drugs, Lupron and Prevacid. However, according to the government's Sentencing Memorandum, the fines paid to compensate the federal government and the states in connection with the fraudulent scheme only pertained to Lupron®, not Prevacid. Moreover, the fines and civil penalties paid did not compensate plaintiff and the Class º 2003 KLINE & SPECTER 13

for their losses. It is believed and therefore averred that defendants TAP, Abbott and Takeda engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.

- 36. Defendant, Bayer Corporation ("Bayer"), is a highly diversified healthcare company whose principal business is the development, manufacture and sale of healthcare products and services, including pharmaceuticals. Bayer is located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205-9741.
- Defendant, Bayer AG ("Bayer AG"), is the parent company of Bayer, the subsidiary in the United States that markets, sells and distributes prescription drugs to clinicians nationwide.

  Bayer AG is a German corporation with its headquarters located at 51368 Leverkusen, Germany.

  Bayer AG acquired Cutter Laboratories, Inc. ("Cutter") in 1974 and Miles Laboratories, Inc. ("Miles") in 1978 and the two companies are now subsidiaries of Bayer AG.
- 38. Defendants Bayer AG, Bayer, Miles and Cutter [hereinafter the "Bayer Defendants"] are manufacturers, sellers and distributors of, among other things, prescription drugs used in the treatment of cancer, among other types of prescription drugs. One of the Bayer Defendants' drugs is Viadur\* (leuprolide acetate implant), which is similar to Zoladex\* and Lupron\*. The Bayer Defendants license Viadur\* from Alza Corporation, another defendant herein, and then the Bayer Defendants market and distribute the drug. The Bayer Defendants also are involved in the manufacturing, marketing, sales and distribution of drugs used to treat hemophilia, including KoaTE\*, Kogenate and KONyNE\*, among other drugs.
- 39. In January 2002, Bayer, like TAP and the AstraZeneca Defendants, agreed to plead guilty to federal criminal charges and to settle with the DOJ, paying fines and penalties totaling more

than \$257 million relating to the federal criminal investigation of Bayer. It is believed and therefore averred that the Bayer Defendants engaged in unlawful conduct similar to that of the other defendants herein with respect to their marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.

- 40. Defendant, Glaxo Wellcome, P.L.C. ("GlaxoSmithKline"), is an English public limited company incorporated on December 6, 1999 under English law, with its corporate headquarters located at 980 Great West Road, Brentford, Middlesex, TW8 9GS, England. GlaxoSmithKline P.L.C. ("GlaxoSmithKline") was formed on December 27, 2000 with the merger of Glaxo Wellcome, P.L.C. and SmithKline Beecham, P.L.C., both English public limited companies. GlaxoSmithKline P.L.C. has its operational headquarters at One Franklin Plaza, 200 North 16th Street, Philadelphia, Pennsylvania 19102, and at Research Triangle Park, North Carolina 27709. GlaxoSmithKline conducts extensive business, including the sale of pharmaceuticals that are the subject of the scheme alleged herein.
- 41. Defendant, SmithKline Beecham Corporation ("SmithKline"), a wholly owned subsidiary of GlaxoSmithKline P.L.C. is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 200 North 16<sup>th</sup> Street, Philadelphia, Pennsylvania 19102. SmithKline conducts extensive business, including the sale of pharmaceuticals that are the subject of the scheme alleged herein.
- 42. Defendant, Glaxo Wellcome, Inc. ("Glaxo"), a wholly owned subsidiary of GlaxoSmithKline P.L.C., is a North Carolina corporation with its principal place of business at 5 Moore Drive, Research Triangle Park, North Carolina 27709. Glaxo conducts extensive business, including the sale of pharmaceuticals that are the subject of the alleged scheme herein.

- 43. Defendants, GlaxoSmithKline, SmithKline and Glaxo [hereinafter the "GlaxoSmithKline Defendants"], are manufacturers, sellers and distributors of cancer, inhalation and miscellaneous other drugs. One such drug used in connection with cancer treatment is the antiemetic drug, Zofran® (ondansetron). Prior to the Glaxo/SmithKline merger, one of SmithKline's drugs was the antiemetic, Kytril® (granisetron), which is now one of Hoffman La-Roche's drugs, another defendant herein. GlaxoSmithKline is also involved in the manufacture, marketing, sales and distribution of inhalation drugs used in the treatment of asthma, namely Ventolin® and Flovent® (albuterol sulfates). Like TAP, the AstraZeneca Defendants and Bayer, the GlaxoSmithKline Defendants have agreed to resolve the federal criminal investigation of them and to pay fines and civil penalties totaling more than \$86 million. It is believed and therefore averted that the GlaxoSmithKline Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer, inhalation and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 44. Defendant, Pharmacia Corporation ("Pharmacia"), is a Delaware corporation located at 100 Route 206 North, Peapack, New Jersey 02977. Pharmacia was created in April 2000 through the merger of Pharmacia & Upjohn ("P&U") with Monsanto Company ("Monsanto") and its G.D. Searle ("Searle") unit. Pharmacia manufactures, sells and distributes various cancer and miscellaneous other drugs.
- 45. Defendant, G.D. Searle Company a/k/a G.D. Searle & Co. ("Searle"), is a Delaware corporation with its principal place of business located at 5200 Old Orchard Road, Skokie, Illinois 60077. Searle became a subsidiary of Pharmacia in the 1999 Monsanto-P&U merger. Searle manufactures, distributes and sells pharmaceutical drugs that are the subject of the scheme alleged herein.

- Defendants Pharmacia, P&U, Monsanto and Searle [hereinafter collectively "the Pharmacia Defendants"], are manufacturers, sellers and distributors of, among other things, a prescription drug known as Trelstar™ Depot (triptorelin pamoate), which is similar to TAP's Lupron®, AstraZeneca's Zoladex®, and Bayer's Viadur®, concerning the treatment of prostate cancer, and another drug Synarel® (nafarelin acetate) which is similar to Lupron®, Zoladex® and Viadur® in connection with treatment of endometriosis in women and central precoclous puberty in children. Adriamycin® (doxorubicin) is a cancer drug manufactured and sold by the Pharmacia defendants, among others. It is believed and therefore averred that the Pharmacia Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of eancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 47. Defendant, Sanofi-Synthelabo Inc. ('Sanofi"), is a French corporation located at 174, avenue de France, 75013 Paris, France, which has designated its 90 Park Avenue, New York, New York location as its commercial headquarters in the United States and the address where service upon its authorized agent can be made. Additionally, Sanofi maintains its North American pharmaceutical research and development headquarters at 11 Great Valley Parkway, Malvern, Pennsylvania 19355. Sanofi manufactures, markets, promotes, sells and distributes various cancer and miscellaneous other drugs. Among these products is Eligard™ (leuprolide acetate) which is similar to Lupron♥, Zoladex♥, Viadur♥ and Trelstar™. It is believed and therefore averred that Sanofi has engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales, and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.

- 48. Defendant, Johnson & Johnson ("J&P"), is a highly diversified healthcare corporation organized and existing under the laws of the State of New Jersey with a principal place of business and corporate headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all times material hereto, J&J, by and through its wholly-owned subsidiary companies, and their respective officers, directors, employees and agents, was in the business of manufacturing, promoting, marketing, distributing and selling healthcare products and services to medical providers, among others.
- 49. Defendant, Alza Corporation ("Alza"), is a wholly-owned subsidiary company of Defendant J&J as of June 22, 2001, and has its corporate headquarters in Mountain View, California. Alza develops, manufactures and licenses Viadur<sup>®</sup>, among other drugs, a bioequivalent drug to Lupron<sup>®</sup>, Zoladex<sup>®</sup>, Trelstar<sup>™</sup>, and Eligard<sup>™</sup>, which is used in the treatment of prostate cancer.
- 50. Defendant, Centocor, Inc. ("Centocor"), is a Pennsylvania corporation and has been a wholly owned subsidiary of Defendant J&J since its acquisition by J&J in October 1999. Centocor's principal place of business is located at 244 Great Valley Parkway, Malvem, Pennsylvania 19355-1312. Centocor manufactures, distributes, markets and sells prescription drugs to providers nationwide, including pharmaceuticals that are the subject of the scheme alleged herein, such as Remicaid.
- 51. Defendant, Ortho Biotech ("Ortho"), is a New Jersey corporation and has been a wholly owned subsidiary of Defendant J&J since its formation by J&J in 1990. Ortho's principal place of business is located at 700 U.S. Highway, Route 202 South, Raritan, New Jersey 08869. Ortho is a biotechnology company. Ortho manufactures, distributes, markets and sells prescription drugs to providers nationwide, including pharmaceuticals that are the subject of the scheme alleged herein, such as Procrit® (epoetin alfa).

- 52. Defendant, J&J, along with its various other affiliated and subsidiary companies. including Centocor, Ortho, and Alza [hereinafter collectively "the J&J Defendants"], manufactures. distributes, markets and sells cancer and miscellaneous other drugs. It is believed and therefore averred that the J&J Defendants have engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and/or distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 53. Defendant, Alpha Therapeutic Corporation ("Alpha"), is a California corporation with its corporate headquarters located at 5555 Valley Boulevard, Los Angeles, California 90032-3520. Alpha develops, manufactures, markets, distributes and sells biopharmaceutical products such as Factor VIII. It is believed and therefore averred that Alpha engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of miscellaneous other drugs that are paid for by plaintiff and the Class.
- 54. Defendant, Hoffman LaRoche, Inc., ("Hoffman"), is a corporation with its principal place of business at 340 Kingsland Street, Nutley, NJ 07110. Hoffman manufactures, markets, distributes and sells cancer and miscellaneous other drugs, which are the subject of the scheme alleged herein. Among others, Hoffman sells the cancer drug Kytril<sup>6</sup>, which it acquired from GlaxoSmithKline as part of the merger of Glaxo and SmithKline in 2000, and the cancer drugs Roferon A (interferon 2-alpha), Vesanoid (tretinoin), and Xeloda (capecitabine). It is believed and therefore averred that Hoffman engaged in unlawful conduct similar to that of the other defendants with respect to its marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 55. Defendant, Amgen, Inc. ("Amgen"), is a California corporation with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen is °2003 KLINE & SPECTER

a biotechnology company that develops, manufactures, distributes, markets and sells cancer and miscellaneous other drugs, which are the subject of the scheme alleged herein.

- 56. Defendant, Immunex Corporation ("Immunex"), is a biopharmaceutical company with its principal place of business located at 51 University Street, Seattle, Washington 98101. Immunex was acquired by Amgen, Inc. on July 15, 2002. Immunex manufactures, distributes and sells pharmaceutical drugs that are the subject of the alleged scheme herein.
- 57. Defendants, Amgen and Immunex [hereinafter the "Amgen Defendants"], are manufacturers, sellers and distributors of, among other things, cancer and miscellaneous other drugs. It is believed and therefore averred that the Amgen Defendants engaged in unlawful conduct similar to that of the other defendants with respect to its marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- Defendant, Aventis Pharmaceuticals, Inc. ("Aventis"), is a Delaware corporation with its corporate headquarters at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey, 08807-2854. Aventis was formerly known as Hoechst Marion Roussel, Inc. ("Hoechst"). Aventis is the United States pharmaceutical business of Aventis S.A. Aventis S.A. was created on December 15, 1999 through the merger of Hoechst A.G. and Rhône-Poulenc S.A. Also on this date, the subsidiaries of Hoechst A.G. and Rhône-Poulenc S.A., Hoechst Marion Roussel A.G. and Rhône-Poulenc Rorer Inc. formed Aventis Pharma A.G. The United States pharmaceutical business of Aventis Pharma A.G. is Aventis Pharmaceuticals, Inc. Aventis manufactures and distributes cancer and miscellaneous other drugs.
- 59. Defendant, Aventis Behring L.L.C. ("Aventis Behring"), is an Illinois limited liability corporation with its principal place of business at 1020 First Avenue, King of Prussia, Pennsylvania, 19406. Aventis Behring was formerly known as Centeon, L.L.C. Aventis Behring conducts 2003 KLINE & SPECTER 20

extensive business, including the sale of pharmaceuticals that are the subject of the scheme alleged herein.

- Defendant, Hoechst Marion Roussel, Inc. ("Hoechst"), prior to its acquisition by 60. Aventis, was a Delaware corporation with its principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri, 64137-1405. Hoechst conducts extensive business, including the sale of pharmaceuticals that are the subject of the scheme alleged herein.
- 61. Defendant, Centeon L.L.C. ("Centeon"), was formerly a 50/50 joint venture with Aventis Behring. On January 10, 1996, Hoechst AG and Rhone-Poulenc Rorer formed Centeon. Centeon was headquartered in King of Prussia, Pennsylvania. Centeon was formerly known as Armour Pharmaceuticals Co. Centeon conducted extensive business, including the sale of pharmaceuticals that are the subject of the scheme alleged herein.
- Defendant, Armour Pharmaceuticals ("Armour"), is a subsidiary of Rhone-Poulenc 62. Rorer, with headquarters at 500 Arcola Road, Collegeville, PA 19426-3909. Armour is a global pharmaceutical company which develops, manufacturers and markets drugs, including the sale of pharmaceuticals that are subject of the scheme alleged herein.
- Defendants, Aventis, Aventis Behring, Hoechst, Centeon and Armour [hereinafter 63. the "Aventis Defendants"], are manufacturers, sellers and distributors of, among other things, cancer and miscellaneous other drugs. It is believed and therefore averred that the Aventis Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- Defendant, Baxter International Inc. ("Baxter"), is a Delaware corporation with its 64. principal place of business at One Baxter Parkway, Deerfield, Illinois, 60015. Baxter manufactures 2003 KLINE & SPECTER

and distributes prescription drugs to clinical administrators. Baxter is a global medical products company that develops, manufactures, markets and distributes drugs to treat cancer, trauma, hemophilia, immune deficiencies, infectious diseases, kidney disease and other disorders.

- 65. Defendant, Baxter Healthcare Corporation ("Baxter Healthcare"), is the principal domestic operating subsidiary of Baxter International. Baxter Healthcare is a global medical products and services company with emphasis on blood therapies, cardiovascular medicine, medication delivery and renal therapy.
- 66. Defendant, Immuno-U.S., Inc. ("Immuno"), is a wholly owned subsidiary of Baxter International, Inc. with its principal place of business located at 1200 Parkdale Road, Rochester, MI 48307. Immuno is a bio-pharmaceutical company that develops, manufacturers and distributes drugs that are the subject of the scheme alleged herein.
- 67. Defendants, Baxter, Baxter Healthcare and Immuno [hereinafter the "Baxter Defendants"], are manufacturers, sellers and distributors of, among other things, cancer and miscellaneous other drugs. It is believed and therefore averred that the Baxter Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and/or distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 68. Defendant, Boehringer Ingelheim Corporation ("Boehringer"), is a Nevada corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut, 06877. Boehringer designs, manufactures, markets and distributes pharmaceuticals, including inhalants that are the subject of the scheme alleged herein.
- 69. Defendant, Ben Venue Laboratories, Inc. ("Ben Venue"), is a Delaware corporation with its principal place of business at 300 Northfield Road, Bedford, Ohio, 44146. Ben Venue is a

contract developer and manufacturer of pharmaceuticals and produces generic injectable pharmaceuticals through its Bedford Laboratories division. Boehringer is the United States subsidiary of Boehringer Ingelheim of Germany and acquired Ben Venue in December, 1997. Ben Venue conducts extensive business, including the sale of pharmaceuticals that are the subject of the scheme alleged herein.

- 70. Defendant, Bedford Laboratories ("Bedford"), is a division of Ben Venue with its principal place of business at 300 Northfield Road, Bedford, Ohio, 44146. Bedford manufactures and distributes pharmaceuticals, including pharmaceuticals that are the subject of the scheme alleged herein.
- 71. Defendant, Roxane Laboratories, Inc. ("Roxane"), is a subsidiary of Boehringer with its principal place of business located at Post Office Box 16532, Columbus, Ohio, 43216-6532. Roxane manufactures markets, distributes and sells pharmaceuticals, including pharmaceuticals that are the subject of the scheme alleged herein.
- 72. Defendants, Boehringer, Ben Venue, Bedford and Roxane [hereinafter the "Boehringer Defendants"], are manufacturers, sellers and distributors of, among other things, inhalant and miscellaneous other drugs. It is believed and therefore averred that the Boehringer Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and/or distribution of inhalant and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 73. Defendant, Bristol-Myers Squibb Company ("Bristol-Myers"), is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, New York, 10154. Bristol-Myers is a pharmaceutical and healthcare products company. Bristol-Myers

manufactures, markets, sells and distributes cancer drugs, among other prescription drugs, that are the subject of the scheme alleged herein.

- 74. Defendant, Oncology Therapeutics Network Corporation ("OTN"), is a Delaware corporation with its principal place of business located at 395 Oyster Point Boulevard, Suite 405, South, San Francisco, California, 94080. OTN is a wholly owned subsidiary of Bristol-Myers and distributes cancer drugs, products and services to office-based oncology practices.
- 75. Defendant, Apothecon, Inc. ("Apothecon"), is a division of Bristol-Myers with its principal place of business at 777 Scudders Mill Road, Plainsboro, New Jersey, 08536. Apothecon manufactures pharmaceutical drugs that are the subject of the alleged scheme herein.
- 76. Defendants Bristol-Myers, OTN and Apothecon [hereinafter the "Bristol-Myers Defendants"], are manufacturers, sellers and distributors of, among other things, cancer and miscellaneous other drugs. It is believed and therefore averred that the Bristol-Myers Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 77. Defendant, Dey, Inc. ("Dey"), is a Delaware corporation with its principal place of business located at 2751 Napa Valley Corporate Drive, Napa, California, 94558. Dey manufactures, distributes, markets and sells, among other things, inhalant drugs. On June 13, 2003, it was reported that Dey settled a civil suit with the federal government and the State of Texas for \$18.5 million arising out of Dey's sale and marketing of its prescription drugs. It is believed and therefore averred that Dey engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of inhalant drugs that are paid for by plaintiff and the Class.

- 78. Defendant, Fujisawa Pharmaceutical Co., Ltd. ("Fujisawa"), is a Japanese corporation with its headquarters located at 4-7, Doshomachi 3-Chome, Chuo-ku, Osaka 541-8514, Japan. Fujisawa Ltd. is a pharmaceutical manufacturer which offers a broad range of pharmaceutical products worldwide.
- 79. Defendant, Fujisawa Healthcare, Inc. ("Fujisawa Healthcare"), is a Delaware corporation with its principal place of business located at 3 Parkway North, Deerfield, Illinois, 60015. Fujisawa Healthcare is a wholly owned subsidiary of Fujisawa Pharmaceutical Co., Ltd., Osaka, Japan. Fujisawa Healthcare is a pharmaceutical manufacturer with business concentrations in therapeutics, transplantation, anti-infectives, dermatology and cardiovascular care, among others.
- 80. Defendant, Fujisawa USA, Inc. ("Fujisawa USA"), is a Delaware corporation with its principal place of business located at 3 Parkway North, Deerfield, Illinois, 60015. Fujisawa USA is a wholly-owned subsidiary of Fujisawa. In 1998, Fujisawa Healthcare assumed responsibility for Fujisawa USA's portfolio of proprietary products.
- 81. Defendants, Fujisawa, Fujisawa Healthcare and Fujisawa USA [hereinafter the "Fujisawa Defendants"], are manufacturers, sellers and distributors of, among other things, cancer and miscellaneous other drugs. It is believed and therefore averred that the Fujisawa Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 82. Defendant, Novartis International AG ("Novartis AG"), is a Swiss company with its corporate headquarters located at Lichtstrasse 35, CH-4056, Basel, Switzerland. Defendant Novartis AG was created in 1996 with the merger of Swiss companies Ciba-Geigy and Sandoz

Pharmaceutical Corporation ("Sandoz"). Defendant Novartis AG develops, manufacturers, markets and sells cancer and miscellaneous other drugs that are the subject of the scheme alleged herein.

- 83. Defendant, Novartis Pharmaceutical Corporation ("Novartis"), is a South Dakota corporation with its principal place of business located at One Health Plaza, East Hanover, New Jersey, 07936-1080. Novartis is the United States affiliate of Novartis AG. Novartis develops, manufacturers, markets and sells cancer and miscellaneous other drugs, that are the subject of the scheme alleged herein.
- 84. Defendants, Novartis AG, and Novartis [hereinafter the "Novartis Defendants"], are manufacturers, sellers and distributors of, among other things, cancer and miscellaneous other drugs. It is believed and therefore averred that the Novartis Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 85. Defendant, Schering-Plough Corporation ("Schering-Plough"), is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey, 07033. In June 2003, Schering-Plough revealed that it was going to be criminally indicted for unlawful conduct described herein, including providing free samples of drugs knowing and expecting that doctors and others would bill for them. Schering manufactures, markets and sells prescription drugs, including pharmaceuticals that are the subject of the alleged scheme herein.
- 86. Defendant, Warrick Pharmaceuticals Corporation ("Warrick"), is a Delaware corporation with its principal place of business located at 6100 Neil Road #500, Reno, Nevada, 89511. Warrick is a wholly-owned subsidiary of Schering. Warrick manufactures and sells prescription drugs, including inhalants, that are the subject of the alleged scheme herein.

- 87. Defendants, Schering and Warrick [hereinafter the "Schering Defendants"], are manufacturers, sellers and distributors of, among other things, cancer, inhalant and miscellaneous other drugs. It is believed and therefore averred that the Schering Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer, inhalant and miscellaneous other drugs that are paid for by the plaintiff and the Class.
- 88. Defendant, Sicor, Inc. ("Sicor"), is a Delaware corporation with its principal place of business located at 19 Hughes, Irvine, California 92618. Sicor was created in 1997 with the merger of Gensia, Inc., a finished dosage manufacturer, and Rakepoll Holding, a European-based supplier of pharmaceuticals. Sicor manufactures, markets and sells generic injectable pharmaceutical products that are the subject of the alleged scheme herein.
- 89. Defendant, Gensia Sicor Pharmaceuticals, Inc. ("Gensia"), is a Delaware corporation with its principal place of business located at 17 Hughes, Irvine, California 92618. Gensia is a wholly-owned subsidiary of Sicor and offers products in the fields of oncology, cardiology and anesthesiology. Gensia formed a strategic alliance with Abbott in 1999 to market and distribute oncology products in the United States. In March 2002, Sicor and Abbott restructured their agreement. Gensia develops, manufactures, markets and sells injectable pharmaceuticals.
- 90. Defendants, Sicor and Gensia [hereinafter the "Sicor Defendants"], are manufacturers, sellers and distributors of, among other things, cancer and miscellaneous other drugs. It is believed and therefore averred that the Sicor Defendants engaged in unlawful conduct similar to that of the other defendants with respect to their marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.

- 91. Defendant, Wyeth ("Wyeth"), formerly American Home Products Corporation, is a Delaware corporation with its principal place of business located at Five Giralda Farms, Madison, New Jersey, 07940. Wyeth manufactures, markets, and distributes pharmaceutical drugs that are the subject of the alleged scheme herein.
- 92. Defendant, Wyeth Pharmaceuticals ("Wyeth Pharmaceuticals"), formerly Wyeth-Ayerst Laboratories, is a New York corporation with its headquarters located at 500 Arcola Road, Collegeville, Pennsylvania, 19426. Wyeth Pharmaceuticals manufactures, markets, distributes and sells pharmaceutical drugs that are the subject of the alleged scheme herein.
- 93. Defendants, Wyeth and Wyeth Pharmaceuticals [hereinafter the "Wyeth Defendants"], are manufacturers, distributors and sellers of, among other things, cancer and miscellaneous other drugs. It is believed and therefore averred that Wyeth Defendants engaged in unlawful conduct similar to that of the marketing, promotion, sales and distribution of cancer and miscellaneous other drugs that are paid for by plaintiff and the Class.
- 94. Defendant, Saad Antoun, M.D. ("Antoun"), is an individual and resident of the State of New Jersey, and is and was a licensed physician with a specialty in urology, with offices located at 733 North Beers Street, Suite L6, Holmdel, New Jersey 07733. Dr. Antoun was indicted and pled guilty to, among other things, receiving free samples of Zoladex® from the AstraZeneca Defendants and charging his patients for them.
- 95. Defendant, Stanley C. Hopkins, M.D. ("Hopkins"), is an individual and resident of the State of Florida, and is and was a licensed physician with a specialty in urology, with offices located at 2419 South Seacrest Boulevard, Boynton Beach, Florida 33435. Dr. Hopkins was indicted and pled guilty to, among other things, receiving free samples of Zoladex® from the AstraZeneca Defendants and charging his patients for them.

- 96. Defendant, Robert A. Berkman, M.D. ("Berkman"), is an individual and resident of the State of Ohio, and was a licensed physician with a specialty in urology, with offices located at 5969 East Broad, #306, Columbus, Ohio 43213. Dr. Berkman was charged with, among other things, receiving free samples of Zoladex® from the AstraZeneca Defendants and charging his patients for them.
- 97. The acts alleged in this Complaint to have been done by each of the defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.
- 98. Various persons and/or firms, not named as defendants herein, including various medical providers across New Jersey, have participated as co-conspirators in the violations alleged herein and have performed acts and made statements or omissions in furtherance thereof.

#### PLAINTIFF CLASS ALLEGATIONS

99. Plaintiff seek to bring this case as a class action pursuant to Rule 4:32-1 of the New Jersey Rules Governing the Courts, on behalf of themselves and all others similarly situated in New Jersey as members of a proposed class, defined as follows (the "Class"):

All persons and entities in New Jersey and throughout the county who, during the period beginning at least 1991 through the present, paid any portion of the cost of cancer, inhalant and miscellaneous other drugs manufactured, marketed, distributed and sold by Defendants, which cost was based, in whole or in part, upon the published AWPs for such drugs. Excluded from the Class are Defendants, any entity in which a Defendant has a controlling interest, and their legal representatives, heirs, successors, any governmental entities, and any person or entity seeking to make a claim under ERISA, Medicare, or federal law.

# NUMEROSITY

100. The proposed Class is so numerous that joinder of all of its members is impractical. Each year, hundreds of thousands of patients, including men, women, and children are prescribed and pay for cancer, inhalant and miscellaneous other drugs manufactured, marketed, distributed and sold by Defendants at a price which is based, in whole or in part, on the AWPs for such drugs.

# COMMON QUESTIONS OF LAW AND FACT

- 101. Virtually all of the issues of law and fact in this class action are common to the Class and include at least the following:
  - i. Whether the Defendants engaged in the fraudulent marketing and sales scheme and conspiracy as alleged herein;
  - ii. Whether the Defendants unlawfully set the AWPs for cancer, inhalant and miscellaneous other drugs;
    - Whether the Defendants conspired and agreed amongst themselves and with others to raise, fix, maintain or stabilize the AWPs for cancer, inhalant and miscellaneous other drugs;
    - iv. Whether the conspiracy was implemented;
    - Whether the Defendants unlawfully marketed and promoted the spreads between the AWPs and the actual costs for their drugs to medical providers and others;
    - vi. Whether the Defendants provided free samples of their drugs to medical providers and others and/or otherwise distributed such free samples;
    - vii. Whether the Defendants encouraged medical providers and others to charge patients for free samples provided by sales representatives, and/or otherwise knew or expected that medical providers and others would in fact charge patients for such free samples;
    - viii. Whether the Defendants engaged in a conspiracy and/or a pattern and practice of deceiving and defrauding the Class and concealing their unlawful conduct and conspiracy;

- ix. Whether the Defendants provided other inducements to medical providers and others to get them to prescribe Defendants' drugs;
- x. Whether the Defendants engaged in a conspiracy and/or concerted conduct designed to avoid efforts to reduce the costs of prescription drugs;
- xi. Whether the Defendants violated the consumer protection laws of New Jersey;
- xii. Whether plaintiff and the members of the Class are entitled to compensatory damages, and, if so, the nature of such damages;
- xiii. Whether plaintiff and members of the Class are entitled to declaratory and injunctive relief as to Defendants' conduct; and
- wiv. Whether plaintiff and members of the Class are entitled to an award of punitive damages, reasonable attorneys' fees, prejudgment interest, post-judgment interest, costs of suit, and other appropriate relief under the circumstances of this case.

#### TYPICALITY

102. Plaintiff' claims are typical of the claims of other members of Class. Plaintiff and all members of the Class sustained damages. The losses of each member of the Class were directly caused by the Defendants' fraudulent marketing and sales scheme and conspiracy.

#### ADEQUACY OF REPRESENTATION

103. Plaintiff can and will fairly and adequately represent and protect the interests of the Class and plaintiff has no interests that conflict with or are antagonistic to the interests of Class members. Plaintiff has retained attorneys competent and experienced in class actions, including consumer fraud and protection class actions. No conflict exists between plaintiff and the Class members.

#### SUPERIORITY

- 104. A class action is superior to any other available method for the fair and efficient adjudication of this controversy and common questions of law and fact overwhelmingly predominate over any individual questions that may arise.
- 105. The prosecution of separate actions by individual members of the plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for the Defendants which would, as a practical matter, be dispositive of the claims of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.
- 106. Defendants have acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

#### FACTUAL BACKGROUND

107. Defendants, in the course of operating their pharmaceutical manufacturing, distribution, marketing and sales businesses, and engaging in the sale of same to plaintiff and the Class, either directly or through the medical providers of plaintiff and the Class, offered for sale the pharmaceuticals referenced herein, and others not specifically referenced herein.

#### AWP INFLATION AND UNLAWFUL PROMOTION OF "SPREADS"

- 108. Defendants engaged in a fraudulent scheme and conspiracy to deliberately inflate the AWPs for cancer, inhalant and miscellaneous other drugs and other prescription drugs. The AWP is used by government and private assistance programs for reimbursement.
- 109. Government and private assistance programs have announced publicly that they would use the AWP published in pharmaceutical industry publications as a basis for reimbursement,

in whole or in part. Specifically, reimbursement for cancer, inhalant and miscellaneous other drugs under these programs is based, either in whole or in part, on the AWP reflected in pharmaceutical industry publication sources, such as the *Red Book* which is published in Montvale, New Jersey.

- 110. The *Red Book* and other publications set forth the AWPs for the various dose forms of defendants' drugs. However, in periodically announcing the AWPs for those drugs, the *Red Book* and other publications simply published the prices that were supplied to them by the defendants. Defendants knew that they could, and did directly, control and raise the AWP for their drugs at any time simply by forwarding to the *Red Book* and other publications a new and higher AWP.
- 111. There are significant discrepancies between the AWPs set by the defendants for cancer, inhalant and miscellaneous other drugs and reported in the *Red Book* and other publications, and the prices charged for these drugs by the defendants to medical providers and other suppliers. The AWPs for these drugs is set by the defendants pursuant to a standard industry formula that causes the AWPs to be substantially higher than the actual cost for these drugs to medical providers and other suppliers.
- provider or other seller, the prescription drug manufacturer defendants created a "spread" between what they set as the AWP and the actual price paid by medical providers and other suppliers for their drugs. Once established, such spreads were then marketed by the defendants as a profit to medical providers and other suppliers and were used to incentivize medical providers and other suppliers to prescribe and sell the particular cancer, inhalant and miscellaneous other drugs over other drugs and other alternative courses of treatment.
- 113. This scheme allowed the defendants to control, as part of their sales, marketing and distribution strategies, how much reimbursement would be collected by medical providers and other

suppliers under government and private assistance programs, from plaintiff and the Class, for cancer, inhalant and miscellaneous other drugs. Defendants deliberately marketed and promoted the sale of their cancer, inhalant and miscellaneous other drugs based on the availability of inflated payments made by government and private assistance programs and their beneficiaries as a result of the available spreads. These spreads were often referred to by defendants in internal documents as "Return To Practice," "RTP," "return on investment," "ROF" and "profit." The defendants even prepared side-by-side comparisons of the spreads available on their drugs versus their competitor's drugs in order to promote the higher profits available by choosing one drug over another. These comparisons were used by company sales representatives as marketing and sales tools for use with medical providers and other suppliers. As a result, senior citizens, patients with cancer and many other ailing and infirm Class members who took the prescription drugs manufactured, distributed, marketed and sold by the defendants, and paid some or all of the cost of these drugs, which cost was based in whole or in part on inflated AWPs, have paid millions of dollars in inflated drug prices. Plaintiff and the Class likewise paid more for these drugs than it otherwise should have as a result of defendants' conduct.

#### FREE SAMPLE FRAUD

- 114. Defendants' fraudulent scheme also involved providing free samples of their drugs to medical providers and others and with the knowledge, expectation and encouragement that medical providers would bill Government Assistance, Private Assistance, and No Assistance Patients, for such free samples. Such conduct is civilly fraudulent and criminal.
- 115. Defendants, TAP, Abbott and Takeda, through TAP, admitted the criminality of their involvement in such fraudulent conduct by TAP pleading guilty to having provided free samples to medical providers and having conspired with medical providers to charge patients for such free

samples. As a result, Government, Private and No Assistance Patients, paid the full cost for Lupron® and Prevacid® that should have been free. Moreover, no New Jersey consumer has been compensated for his or her losses as a result of this conduct.

- 116. Several urologists have pleaded guilty to federal Criminal Informations charging them with participating in the conspiracy with TAP to commit free sample fraud as described herein. At the time of this Complaint, the following medical providers have all been indicted, and most have pleaded guilty, for participating in a conspiracy with TAP to commit free sample fraud, among other things:
  - i. Dr. John Romano of Plymouth, Massachusetts;
  - ii. Dr. Joel S. Olstein of Lewiston, Maine;
  - iii. Dr. Rodney Mannion of LaPorte and Michigan City, Indiana;
  - iv. Dr. Jacob Zamstein of Bloomfield, Connecticut; and
  - v. Dr. Joseph Spinella of Bristol, Connecticut.
- 115. In addition, as set forth more fully below, other defendants provided free samples of their drugs to medical providers and others for which plaintiff and the Class were charged fraudulently.
- in Holmdel, New Jersey, Dr. Saad Antoun, one in Boynton Beach, Florida, Dr. Stanley C. Hopkins, and one in Columbus, Ohio, Dr. Robert A. Berkman all have been criminally indicted for having received free samples of Zoladex from the AstraZeneca Defendants and charging their patients for them with the knowledge of and encouragement by the AstraZeneca Defendants. Dr. Antoun and Dr. Hopkins pleaded guilty to the crime charged. The AstraZeneca Defendants were indicted for and pled guilty to free sample fraud.

- 117. Similarly, the Amgen Defendants have engaged in free sample fraud. National Medical Care, Inc. a purchaser of drugs from the Amgen Defendants, pled guilty to having received free samples of Epogen® from Amgen and billing Medicare and Medicare patients for these drugs.
- 118. The Schering Defendants also have engaged in free sample fraud, having been notified recently by the federal government that they will be indicted for free sample fraud, among other things, as described herein.
- AstraZeneca Defendants provided medical providers, such as those listed above, with free samples and other financial incentives as inducements to increase the usage of Lupron® and Zoladex®, respectively. See, e.g., United States of America v. Spinella, (D. Mass. Dec. 8, 2000); United States of America v. Mannion, (D. Mass. Feb. 28, 2000); United States of America v. Zamstein, (D. Mass. Nov. 3, 2000); United States of America v. Olstein, (D. Mass. April 11, 2001) ("Criminal Informations"); United States of America v. Antoun, No. 02-CR-13-ALL (D. Del., Jan. 15, 2002) ("Criminal Informations"). It is believed and therefore averred that medical providers and others in New Jersey were similarly provided with free samples by defendants and encouraged to bill plaintiff and the Class for them.
- 120. Such inducements caused medical providers to prescribe certain cancer, inhalant and miscellaneous other drugs over competitor drugs, and over potentially alternative courses of treatment, such as surgery, radiation and other non-drug therapies. For instance, medical providers treating patients with prostate cancer were induced to prescribe Lupron<sup>®</sup>, Zoladex<sup>®</sup>, Viadur<sup>®</sup>, Trelstar<sup>™</sup> and Eligard<sup>™</sup>, as opposed to recommending a less expensive and equally or more effective treatment.

121. Once these medical providers switched their patients to the cancer, inhalant and miscellaneous other drugs of the defendants, they then charged their patients the AWP for these drugs for future injections. As a result, the defendants profited from greater sales of their drugs, while medical providers profited from the spreads between the AWPs for these drugs and the actual cost they paid for the drugs. It is believed and therefore averred that all defendants engaged in similar conduct to induce medical providers to prescribe their drugs over competitor drugs, and over potentially alternative courses of treatment.

#### OTHER INDUCEMENTS TO PURCHASE DRUGS

- 122. Defendants also have provided and/or arranged for many other inducements to stimulate sales of cancer, inhalant and miscellaneous other drugs at the expense of plaintiff and the Class. Such inducements included, but were not limited to, kickbacks to medical providers, which consisted of cash payments, free drugs, trips to resorts, free consulting services to doctors and other customers, golf outings and other free entertainment, free continuing medical education courses, and debt forgiveness, among other things.
- 123. All defendants engaged in the practice of providing such inducements to medical providers in furtherance of their fraudulent marketing and sales scheme and conspiracy.
- 124. This fact was confirmed in April, 2002 when the trade association of the pharmaceutical industry, PhRMA, adopted a new marketing code to govern the pharmaceutical industry's relationships with physicians and other healthcare professionals. The voluntary code took effect on July 1, 2002.
- 125. Despite the adoption of this voluntary code, it is believed and therefore averred that defendants have continued the practice of providing inducements to medical providers in furtherance of their fraudulent scheme and conspiracy.

- 126. In October, 2002, the Office of Inspector General for the federal government adopted a Draft Compliance Guideline respecting the provision of such inducements by defendants to medical providers. The Draft Compliance Guideline prohibited and/or significantly curtailed many of the aforesaid inducements.
- 127. Despite the promulgation of such Draft Compliance Guideline, it is believed and therefore averred that defendants have continued the practice of providing such inducements to medical providers in furtherance of their fraudulent scheme and conspiracy.
- 128. One such inducement which has been specifically prohibited by both the Voluntary Compliance Code and the Draft OIG Compliance Guideline is the provision of free samples with the knowledge and expectation that physicians would bill their patients for the same, an inducement which both TAP and the AstraZeneca Defendants have admitted they used with medical providers and others and for which they were criminally indicted. Despite the prohibitions against this practice, the practice continues as to one or more defendants, as set forth more fully herein.

# FEDERAL GOVERNMENT'S RECOVERY OF CRIMINAL FINES AND CIVIL PENALTIES AND DAMAGES SOUGHT HEREIN

TAP, Abbott, Takeda, the Bayer Defendants the GlaxoSmithKline Defendants and the AstraZeneca Defendants, principally has sought to recover only the federal government's portion of the fraudulent charges caused by the defendants, which represents up to 75-80% of the overpayments caused by defendants to federal government assistance program recipients, depending on the program. For instance, CHAMPUS provided reimbursement of 75% of the cost of certain cancer, inhalant and miscellaneous other drugs, while Medicare provided reimbursement of 80% of the cost of certain of these drugs.

- 130. While a portion of the federal settlement proceeds has been returned to the states, plaintiff and the Class have not been compensated for any losses incurred from these settlements.
- 131. Moreover, since the federal government has not investigated, charged and/or settled with all of the pharmaceutical companies alleged herein to be involved in the fraudulent scheme to inflate the AWPs of their drugs and to promote spreads, absent this litigation, plaintiff and the Class would not be able to recover the amounts that it overpaid.
- 132. Absent this litigation, Class members classified as Government Assistance Patients would not recover from defendants the balance of the 20-25% overpayments they made through co-payment and/or deductible amounts paid under federal and state government assistance programs.
- 133. Absent this litigation, Private Assistance Patients, who also over paid for cancer, inhalant and miscellaneous other drugs through co-payment and/or deductible amounts, would not recover.
- 134. Absent this litigation, No Assistance Patients, who paid up to the full price for cancer, inhalant and miscellaneous other drugs, would not recover.
- 135. Furthermore, absent this litigation, plaintiff and the Class who paid for free samples of defendants drugs, as a result of the wrongful inducement by the defendants, would not recover.

# DEFENDANTS' CONSPIRACY AND FRAUDULENT CONCEALMENT

136. Defendants conspired and agreed to accomplish the fraudulent marketing and sales scheme set forth herein in order to increase the sales of their drugs, profits, and market shares, and they committed acts in furtherance of this conspiracy which are outlined in this Complaint to fulfill these goals.

- 137. In furtherance of this scheme and conspiracy to defraud plaintiff and the Class, defendants created centralized, national, marketing, distribution and sales plans which were implemented through their employees and agents in the following manner, among others:
  - Setting the actual average wholesale prices (or list prices) at which cancer,
     inhalant and miscellaneous other drugs were sold;
  - b. Setting the AWPs for these drugs in the Red Book and other similar publications at levels which were materially greater than the actual average wholesale prices (or list prices) for these drugs in order to create "spreads";
  - c. Contacting the *Red Book* and other industry publications for the purpose of setting and controlling the AWPs;
  - d. Contacting medical providers about both the reported AWPs, the actual average wholesale prices (or list prices, and the spreads) for these drugs;
  - c. Creating and disseminating marketing and sales materials that showed the spreads between the reported AWPs and the actual average wholesale prices (or list prices);
  - f. Establishing and offering discounts off of the actual average wholesale prices (or list prices) for their drugs to create even greater spreads for their drugs;
  - g. Providing massive amounts of free samples of their drugs to medical providers with the knowledge, expectation and encouragement that such providers would bill plaintiff and the Class for them;
  - h. Creating and disseminating marketing and sales materials to medical providers and others which discussed how billing for free samples could lower acquisition costs and increase profits;

- Creating and disseminating marketing and sales materials to medical providers and others which discussed other inducements available from defendants for prescribing defendants' drugs;
- j. Inducing plaintiff and the Class to pay inflated payments for cancer, inhalant and miscellaneous other drugs based upon the inflated AWPs established by defendants and to pay for free samples of these drugs;
- k. Distributing cancer, inhalant and miscellaneous other drugs with knowledge and in furtherance of this scheme;
- 1. Receiving the proceeds and benefits of their fraudulent scheme;
- m. Working in concert to circumvent efforts to reduce the costs of cancer, inhalant and miscellaneous other drugs by the government.
- controlling the process and methodology by which the AWP was set as well as the actual average wholesale prices (or list prices) for their drugs. Defendants also prevented plaintiff and the Class from knowing what the actual acquisition costs to medical providers and others for their drugs were, and they failed to inform plaintiff and the Class of their provision of free samples of such drugs and other inducements to medical providers and others to induce them to prescribe cancer, inhalant and miscellaneous other drugs. Moreover, defendants' fraudulent conduct was of such a nature as to be self-concealing.
- 139. Plaintiff and the Class were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice or learn of the factual basis for its claims in this Complaint or their injuries suffered therefrom until recently.

- 140. By reason of the foregoing, the claims of plaintiff and the Class are timely under any applicable statute of limitations pursuant to the discovery rule and the doctrine of fraudulent concealment.
- 141. The defendants have been aware of their unlawful conduct and conspiracy since at least 1991, and probably before that time.
- 142. Despite this knowledge and awareness, the defendants have continued to promote and sell cancer, inhalant and miscellaneous other drugs at artificially inflated prices, and to give away free samples of their drugs knowing and expecting that doctors would bill patients for them.
- 143. The defendants' failure to properly disclose their unlawful conduct and conspiracy, and other acts and omissions as alleged herein, was and is willful, intentional, wanton, malicious, outrageous, and was and continues to be undertaken in deliberate disregard of, or with reckless indifference to, the rights and interests of plaintiff and the Class.

#### **DEFENDANTS' UNLAWFUL CONDUCT IN NEW JERSEY**

- 144. By virtue of the agreement of many of the defendants and third party medical providers herein to plead guilty to conspiracy relating to the sale of cancer, inhalant and miscellaneous other drugs, and to pay fines to resolve both criminal and civil charges against them, it is clear that the conduct of these and other defendants had an effect upon plaintiff and the Class.
- 145. These defendants' guilty pleas and settlements included the sum of more than \$890 million from TAP, Abbott and Takeda to be paid to the United States and 50 states, including the District of Columbia, \$257 million from Bayer to the United States and 47 states, \$86 million from GlaxoSmithKline and \$350 million from AstraZeneca. The Schering Defendants have been notified of an impending indictment by the federal government. Accordingly, such defendants have agreed.

and/or have been apprised, either explicitly or implicitly, that their unlawful conduct and conspiracy has affected the plaintiff and the Class Consumers as more specifically set forth herein.

## THE ASTRAZENECA DEFENDANTS', DR. ANTOUN'S, DR. HOPKINS' AND DR. BERKMAN'S UNLAWFUL CONDUCT IN NEW JERSEY

- 146. It is believed and therefore averred that the AstraZeneca Defendants, along with defendants Dr. Antoun, Dr. Hopkins and Dr. Berkman, engaged in conduct similar to the other defendants with respect to their marketing, promotion, sale and distribution of cancer and miscellaneous other drugs manufactured, distributed, marketed and sold by them. In particular, it is averred that the AstraZeneca Defendants adopted similar unlawful practices, such as the provision of free samples for which doctors could charge and the artificial inflation of the AWPs for their cancer drugs and miscellaneous other drugs, in order to create spreads in their drug prices for the benefit of medical providers and others who purchased AstraZeneca's drugs.
- 147. The drugs manufactured, distributed, marketed and sold by the AstraZeneca Defendants and covered by government and private assistance programs include, but may not be limited to: Zoladex® (goserilin acetate implant), Arimidex® (anastrozole), Casodex® (bicalutamide), Nolvadex® (tamoxifen citrate), Tomudex® (raltitrexed), Diprivan® (propofol), Prilosec® (omeprazole), and Nexium™ (esomeprazole), Cefotan®, Elavil Injection, Faslodex®, Foscavir®, Merrem®, Tenormin Injection and, Xylocaine Injection, among other prescription drugs. Upon information and belief, all of these drugs had "spreads" and were paid for by plaintiff and the Class.
- 148. Zoladex<sup>®</sup> is used in the primary medical treatment of prostate cancer and for the same indications, and therefore in the same patient population, as leuprolide (Lupron<sup>®</sup> TAP, Viadur<sup>®</sup> Bayer, Eligard<sup>™</sup> Sanofi-Synthelabo). In addition, Zoladex<sup>®</sup> may used in this population of patients in combination with the anti-androgen medications, such as bicalutamide (Casodex<sup>®</sup> the

AstraZeneca Defendants) and flutamide (Eulexin® - the Schering Defendants). Tomudex® is used in the treatment of colon cancer, as is irinotecan (Camptosar® - the Pharmacia Defendants).

- 149. One or more of the AstraZeneca Defendants pled guilty to falsely reporting prices for Zoladex\* and conspiring to bill for free samples.
- 150. The guilty plea was not unexpected. In the government's Sentencing Memorandum relating to TAP, AstraZeneca is discussed prominently as having been TAP's major competitor throughout most of the 1990's, both for Lupron® and Prevacid®. AstraZeneca manufactures and sells Zoladex®, a competitor to TAP's Lupron® and Prilosec®, a competitor drug to TAP's Prevacid®. In the Sentencing Memorandum, the government observed:
  - ...in 1995. TAP, in a moment of delicious irony, accused its competitor, the manufacturer of Zoladex, with providing inducements to physicians in violation of the Medicare fraud and abuse laws, to include the fact that employees of the competitor were giving free samples to doctors to encourage them to switch from Lupron to Zoladex. The competitor, in turn, accused TAP of the very same conduct. Top employees from the two companies met in a summit meeting to discuss this exchange of criminal allegations. Did the serious allegations curb TAP's conduct? Did TAP, aware of allegations that its employees had engaged in criminal conduct, undertake expeditiously to stop the behavior, to train its employees in the rules and to enforce their adherence to the rules? Did either company, in possession of information that a competitor was violating the rules, report the conduct to the prosecutive authorities in an effort to clean up the industry? Unfortunately, the answer to all of these questions is no: TAP [and Astra Zeneca] cognizant of the rules and having been accused of violations, simply carried on [their] business as [they] always had, full criminal speed ahead.
- 151. In fact, these cross-allegations of illegal fraudulent conduct by TAP and the AstraZeneca Defendants were levied by the in-house counsel for the companies, thereby making the failure to report the fraud, and the consummation of a conspiracy to engage in a mutual fraudulent scheme, even more egregious.

152. In that same Sentencing Memorandum, the government observed that TAP's own management acknowledged that TAP was not alone in committing the fraudulent scheme and conspiracy in a quote from a TAP employee, who said:

Yes, sure there are rules, but, we operate in a tough competitive marketplace with other pharmaceutical companies. If our employees have to break some rules to win and beat the competition, well, that is what will happen. We have profits to earn and owners to keep happy and bonuses to earn for ourselves and obeying the rules will just have to take a number in line behind all those other priorities. So what if we are breaking the laws: so are our competitors: how can we be expected to follow the rules if they aren't?

- 153. As previously noted, the AstraZeneca Defendants broke the rules time and again and proceeded "full criminal speed ahead" by providing free samples to providers to induce them to use Zoladex® knowing and expecting that providers would bill patients and government and private assistance programs at an artificially inflated AWP. For example, in 1995, the AstraZeneca Defendants proposed to Medical providers that, Zeneca would provide 50 Free Depots (Over \$11,900 Worth of Product) to a particular urology practice for converting the practice's patient's to Zoladex® from Lupron®.
- 154. Another similar proposal was made to Central Indiana Urology which offered \$15,000 in free Zoladex® goods if the practice switched patients to converted to Zoladex® from Lupron®.
- 155. On September 18, 2002, a Holmdel, New Jersey urologist, Saad Antoun, M.D., pleaded guilty to charges of accepting free samples of Zoladex® from the AstraZeneca Defendants with the intent of billing patients and their health insurance providers for those free goods.
- 156. According to the Criminal Indictment against Dr. Antoun, beginning in or about the fourth quarter of 1995 and continuing through at least 1999, Antoun received from the AstraZeneca Defendants, without charge, approximately 195 one-month sample doses of Zoladex. Throughout

that time period, Dr. Antoun prescribed and administered those free doses to patients and submitted claims to government and private insurance programs, receiving reimbursement for administering at least 114 of those free doses.

- 157. Moreover, throughout the same period, the AstraZeneca Defendants and their employees knew and understood: (a) that, because of 'return to practice' (RTP), a doctor who purchased an injection of Zoladex<sup>®</sup> and then billed that injection to government and private insurance programs and to the patient at the published 'average wholesale price' (AWP) for Zoladex<sup>®</sup> rather than at its purchase-price, would earn a substantial profit; and (b) that a doctor who received an injection of Zoladex<sup>®</sup> for free would earn no profit at all from receiving that free dose, assuming that he obeyed the law and did not bill for that dose.
- 158. On December 17, 2002, a Boynton Beach, Florida urologist, Stanley C. Hopkins, M.D., pleaded guilty to charging patients and their health insurers for free samples of Zoladex. Dr. Hopkins admitted to conspiring with the AstraZeneca Defendant to obtain free samples of Zoladex in violation of the PDMA, which, *inter alia*, prohibits billing patients or their insurance carriers for free drug samples.
- 159. According to the Criminal Information against Dr. Hopkins, beginning in or around January 1995 and continuing until at least July 1996, Dr. Hopkins received from the AstraZeneca Defendants, for free, approximately 223 one-month equivalent sample doses of Zoladex. Throughout that time period, Dr. Hopkins prescribed and administered those free doses to patients and submitted claims for at least 152 of those samples to the patients and their insurers and was paid for the prescription of at least 152 of these free dosages.
- 160. On May 19, 2003, a Columbus, Ohio urologist, Robert A. Berkman, M.D., was indicted for engaging in a conspiracy with the AstraZeneca Defendants by accepting 223 free 2003 KLINE & SPECTER 46